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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,334	04/09/2001	Elmar Peschke	1348	8721

7590 05/13/2004
Striker Striker & Stenby
103 East Neck Road
Huntington, NY 11743

EXAMINER

CHISM, BILLY D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/701,334	Applicant(s) PESCHKE ET AL.	
	Examiner B. Dell Chism	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-17 is/are pending in the application.
- 4a) Of the above claim(s) 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Withdrawal of Objections and Rejections

The rejections and/or objections made in the prior office action mailed 28 November 2003, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 01 March 2004 will be addressed to the extent that they pertain to the present grounds of rejection.

Newly submitted claims 14-17 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally filed claims were drawn to in vivo methods of treating hyperinsulinaemia and the claims were searched and considered on those merits. However, new claims 14-17 are drawn to in vitro methods of reducing insulin release from pancreatic islets, which requires different method steps that were not originally considered on the merits and would warrant a separate and distinct search.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 14-17 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 11-13 are currently under consideration.

Claim Rejections - 35 USC § 112

1. (Maintained) Claims 11-13 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is maintained for the reasons stated in the last office action mailed 28 November 2003 and for the following reasons:

The applicants make several arguments however the arguments do not and cannot overcome the rationale as put forward in the previous office action. The specification still lacks evidence in the form of in vivo working examples or guidance required to offer predictable results without an undue quantity of experimentation. The applicants state at page 7 of the 'Response' that "Designing pharmaceutical compositions requires testing to determine preferred effective dosage levels, which requires many more experiments with different concentration levels that are disclosed in the Bailey et al, reference. Perhaps Bailey, et al. should have performed more experiments with in vivo model systems with greater number of melatonin concentrations..." The examiner is not considering the merits per se of the Bailey *et al.* reference, other than to say that Bailey *et al.* casts doubt on the in vivo predictability melatonin use for hyperinsulinaemia. Consequently, the present specification offers nothing along the way of removing the lack of predictability.

Applicants argue on page 8 that "one cannot conclude from the very few in vivo results of Bailey *et al.* that predictability is lacking" regarding the presently claimed in vivo methods of melatonin, however, there is nothing in the specification by way of adequate guidance and/or working examples for in vivo use of melatonin for treating hyperinsulinaemia that would lead one to think otherwise regarding lack of predictability.

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The factors cited in the previous office action point out the lack of predictable and convincing evidence. At the bottom of page 9 of the response, Applicants argue that “excessive insulin production should be suppressed or reduced to a significant extent...” This is merely a prophetic conclusion for in vivo use of melatonin. This does nothing for the lack of guidance and working examples in the present specification. There simply is no predictable evidence in the specification that the process would work within the in vivo environment.

Claim Rejections - 35 USC § 102

2. (Withdrawn) Rejection of Claims 11-13 under 35 U.S.C. 102(e) as being anticipate by Lewy *et al.* is withdrawn as obviated by applicants’ arguments.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(New) Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson *et al.* (US 6,207,190 B1). Richardson *et al.* teaches the use of melatonin as a supplement for glaucoma patients to reduce hyperinsulinaemia (column 12, lines 31-33). Furthermore, Richardson *et al.* teaches a unit dosage composition comprising a hyperinsulinaemia-modulating agent, i.e., melatonin in the amount ranging from about 0.05 mg to about 10 mg. Although Richardson *et al.* does not teach the exact claimed methods of treating hyperinsulinaemia, it would have been obvious to one skilled in the art at the time of invention to determine all operable and optimum component ratios and methods of delivery in the claimed

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composition of Richardson *et al.*, because the component ratios and methods of delivery are an art-recognized result-effective variable that is routinely determined and optimized in the composition/pharmaceutical arts.

Conclusion

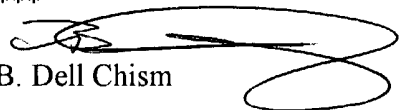
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism



CHRISTOPHER R. TATE
PRIMARY EXAMINER